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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
08/952,574	11/10/1997	Marc Gagne	2283-1-001	9278

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EXAMINER	
DOWELL, PAUL THOMAS	
ART UNIT	**PAPER NUMBER**
1632	

DATE MAILED: 08/09/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	08/952,574	GAGNE, MARC	
	Examiner	Art Unit	
	Paul Dowell	1632	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) 1-18 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) 1-18 are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Claims 1-18 are pending

Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

Group I, claims 1, 2, 6-11, drawn to a method of treatment comprising administering a recombinant DNA expression system comprising at least a DNA sequence encoding for a therapeutic protein or peptide.

Group II, claims 1, 2, 6-11, drawn to a method of treatment comprising administering a recombinant DNA expression system comprising at least a DNA sequence encoding for a therapeutic antisense RNA.

Group III, claims 1, 3-12, drawn to a method of treatment comprising administering a recombinant DNA expression system comprising at least a DNA sequence encoding for a therapeutic protein or peptide wherein said DNA expression system is transgenic recombinant animal cells.

Group IV, claims 1, 3-12, drawn to a method of treatment comprising administering a recombinant DNA expression system comprising at least a DNA

sequence encoding for a therapeutic antisense RNA wherein said DNA expression system is transgenic recombinant animal cells.

Group V, claims 13-18, drawn to a non-human transgenic animal for the production of a recombinant protein or peptide.

Group VI, claims 13-18, drawn to a non-human transgenic animal for the production of a recombinant antisense RNA.

Applicants are required to elect one cell type from claim 4, one infectious disease causing agent from claim 8, one nucleic acid encoding a therapeutic from claim 9 and one nucleic acid encoding a therapeutic from claim 11. Applicants are further required to make the above elections commensurate with the goal of the elected method of treatment. It is noted that this is not a species election since different cell types, disease causing agents and nucleic acids encoding therapeutics are distinct and have distinct structure and function.

Species Election

Claim 15 generic to a plurality of disclosed patentably distinct species of promoter sequences comprising lactoferrin, serum albumin, αS1-casein, αS2-casein, β-casein, κ-casein, α-lactalbumin, whey acidic protein, β-lactoglobulin, cytokines, chemokines and growth factors. Applicant is required under PCT Rule 13.2 to elect a single disclosed species, even though this requirement is traversed.

Claim 16 generic to a plurality of disclosed patentably distinct species of secretory signal sequences comprising lactoferrin, serum albumin, αS1-casein, αS2-casein, κ-casein, α-lactalbumin, β-lactoglobulin, cytokines, chemokines and growth factors. Applicant is required under PCT Rule 13.2 to elect a single disclosed species, even though this requirement is traversed.

Claim 17 generic to a plurality of disclosed patentably distinct species of expression regulatory and secretory signal sequences from human, bovine, caprine, ovine, feline, canine, lagomorphs, birds and fishes. Applicant is required under PCT Rule 13.2 to elect a single disclosed species, even though this requirement is traversed.

According to PCT Rule 13.2, unity of invention exists only when the shared same or corresponding technical feature is a contribution over the prior art. The technical feature linking the inventions of Groups I-VI appears to be a recombinant DNA expression system comprising at least a DNA sequence encoding for a therapeutic protein, peptide or antisense RNA operably linked to a promoter capable of directing the *in vivo* expression of said DNA sequence. However, said technical feature is taught by Flynn et al (Proceedings of the National Academy of Science, USA, 90:11478-11482, 1993) to lack novelty or inventive step because Flynn et al teaches a DNA expression system comprising a nucleic acid encoding influenza virus hemagglutinin glycoproteins that when expressed *in vivo* raises protective immunity against lethal influenza challenges. Therefore, the instant technical feature of Groups I-VI does not make a contribution over the prior art.

Furthermore, while the inventions of Groups I, III and V are related to the inventions of Groups II, IV and VI in sharing a common DNA expression system, they are distinct each from the other because the inventions of Groups I, III and V are drawn to expressing protein/peptide while the inventions of Groups II, IV and VI are drawn to expressing antisense RNA, and protein/peptide have distinct structure and function compared to antisense RNA.

Furthermore, while the inventions of Groups I and II are related to the inventions of Groups III and IV in sharing a common DNA expression system, they are distinct each from the other because they are drawn to methods comprising different steps. For example, the inventions of Groups III and IV require steps involving recombinant animal cells while the inventions of Groups I and II do not.

Furthermore, while the inventions of Groups I, II, III and IV are related to the inventions of Groups V and VI in sharing a common DNA expression system, they are distinct each from the other because the inventions of Groups I, II, III and IV are drawn to methods of treatment while the inventions of Groups V and VI are drawn to transgenic animals.

A search and examination of more than one invention as defined above would unduly burden the Office. Each of the inventions requires a different search of the art and concerns separate considerations of patentability. For example, the subject matter of many of the inventions is not largely co-extensive as the inventions are related to distinct methods of treatment and transgenic animals. Therefore, restriction as defined above is proper.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Paul Dowell whose telephone number is (571)272-5540. The examiner can normally be reached on M-F, 8-4:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ram R. Shukla can be reached on (571)272-0735. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

RAM R. SHUKLA, PH.D.
SUPERVISORY PATENT EXAMINER

Paul Dowell
Art Unit 1632